

a *Sub C2*
2. (Amended) A pharmaceutical composition comprising a pharmaceutically effective amount of N-ethyl-N'-(3-dimethylaminopropyl) urea in combination with a pharmaceutically acceptable carrier.

REMARKS

Claims 1-71 are pending in the present patent application. The Examiner has withdrawn all of the pending claims except for claim 2 based on applicants' election in response to the Examiner's restriction requirement. We are presently investigating whether the named inventors are proper given that claim 2 remains in the present application, and will amend inventorship if necessary. Claim 2 has been amended into an independent claim. Support for the amendment can be found throughout the specification, and more specifically at page 3, lines 18-22, and page 29, line 28 to page 30, line 22. Claim 2, as amended, is directed to a pharmaceutical composition comprising a pharmaceutically effective amount of EDU with a pharmaceutically acceptable carrier.

Claim 2 is rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent 5,506,151 of Ito et al. We respectfully traverse. As discussed in the specification of the present application, the pharmaceutical composition comprising a pharmaceutically effective amount of EDU is to be administered to mammals, including a human, to generally modulate an immune response (page 1, lines 15-18).

In contrast, Ito is directed to the use of secondary and tertiary amines, including EDU, in in-vitro, non-cellular immunoassays to suppress non-specific reactions (col. 1, lines 5-14). Such suppression improves the accuracy and reliability of the quantitative determination of the formation of immunoreactant-complementary immunoreactant complexes such as antigen-antibody complexes. More specifically, EDU is discussed as "useful in suppressing non-specific reactions in immunoassays, particularly immunoassays wherein an immunoreactant is attached covalently or by adsorption to a solid support" (col. 3, lines 47-57). Accordingly, Ito at most discloses an improved analyte solution containing EDU to conduct immunoassays. There is no teaching or suggestion in Ito that EDU can be used as a

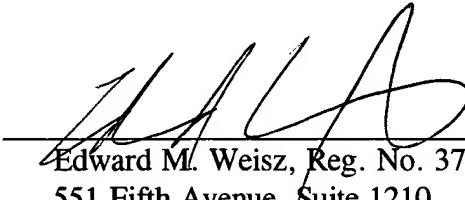
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component of a pharmaceutical composition that is to be administered systemically to a mammal, including a human patient. There is certainly no teaching or suggestion in Ito that EDU is in anyway biologically active when systemically administered so as to be capable of modulating an immune response.

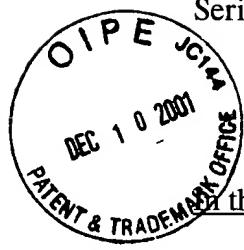
Accordingly, it is respectfully requested that the rejection of claim 2 under 35 U.S.C. § 102 as anticipated by Ito be withdrawn.

Respectfully submitted,
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AMENDMENTS TO THE CLAIMS SHOWING CHANGES

the Claims:

2. (Amended) [The composition of claim 1, wherein the compound is] A pharmaceutical composition comprising a pharmaceutically effective amount of N-ethyl-N'-(3-dimethylaminopropyl) urea in combination with a pharmaceutically acceptable carrier.